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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,561	03/30/2004	David Milton Hadley	330498001US	1223

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EXAMINER

JOHNSON, SHEVON ELIZABETH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,561

Applicant(s)

HADLEY ET AL.

Examiner

Shevon E. Johnson

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-22 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 23-26 and 31 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 27-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/30/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. "Determining a heart rate according to an R-R interval and a P-Q interval" critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claim 4 is also rejected since it depends upon rejected claim 3.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected to because the alternative language "and/or" in line 2 causes confusion in the computation of the polynomial. Therefore the "and/or" should be deleted and replaced with "and." Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Xue et al. (U.S. Patent No. 5,792,065), as cited by the examiner.

In regards to claims 1 and 23, Xue et al. discloses a method and system of processing data for conditioning T-wave segments of a waveform used in estimating T-wave alternans (col. 3, lines 26 – col. 4,

line 5), comprising: ascertaining T-wave segments from a physiologic signal having substantially repetitive (T-wave) waveforms of a heart beat; determining a correction factor [$f(T_{peak})$] based on a set of the repetitive (T-wave) waveforms and a reference (template) waveform (col. 6, lines 17-27); and applying the correction factor to the T-wave segments to compensate for noise in the signal (col. 6, line 39-43; figs. 1-8).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 2 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue '065 in view of Cohen (U.S. Patent No. 4,802,491), as cited by the applicant.**

In regards to claims 2 and 25, Xue discloses the system and method wherein ascertaining T-wave segments comprises (a) determining an average/median beat estimate having a QRS complex and a T-wave segment (col. 6, line 42 – col. 7, line 4). Xue fails to disclose cross-correlating the QRS complexes of the repetitive waveforms with the QRS complex of the average/median beat estimate to align the beats. However, Cohen teaches cross-correlating the QRS complexes of the repetitive waveforms with the QRS complex of the average/median beat estimate to align the beats (col. 6, line 47 – col. 7, line 30; fig. 1).

One having ordinary skill in the art would appreciate that Xue and Cohen could be combined since they both teach a system and method of obtaining consistent measurements in ECGs by eliminating the noise, and thus the references are analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Xue to include cross-correlating the QRS complexes of the repetitive waveforms with the QRS complex of the average/median beat estimate to align the beats as taught by Cohen in order to ascertain T-wave segments.

7. **Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xue '065 in view of Lander (U.S. Patent No. 5,827,195), as cited by the examiner.**

In regards to claim 24, Xue discloses the system and method substantially as claimed as shown above except for a stress test device and electrodes for recording the physiologic signal. However, Lander teaches a stress test device and electrodes for recording the physiologic signal (col. 5, lines 22-47).

One having ordinary skill in the art would appreciate that Xue and Lander could be combined since they both teach a method and apparatus for reducing noise in a signal, and thus the references are analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Xue reference to include a stress test device and electrodes for recording the physiologic signal as taught by Lander in order to provide as a bases to detect variations in the ECG activity to prevent cardiac disorders (col. 4, lines 45-64).

Allowable Subject Matter

Claims 9-22 are allowed. The following is a statement of reasons for the indication of allowable subject matter: Combinations cited in claims including but not limited to comparing the representative waveform with individual isolated waveforms to determine a correction factor having an amplitude gain correction factor $G(m)$ and/or a DC shift correction factor $C(m)$; and (d) establishing a correction curve fit to the correction factor from the isolated individual waveforms are not represented in the prior art.

Claims 5-7 and 27-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson
Art Unit 3766


Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766